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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/068,612	02/06/2002	James A. Thomson	960296.97923	6809

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EXAMINER	
WOITACH, JOSEPH T	

ART UNIT	PAPER NUMBER
1632	

DATE MAILED: 07/01/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/068,612	THOMSON ET AL.	
	Examiner	Art Unit	
	Joseph T. Woitach	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-6 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-6 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on February 6, 2002 is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

This application filed February 6, 2002 claims benefit to provisional application 60/266,662 filed February 6, 2001.

Claim 1-6 are pending and currently under examination.

Specification

The nucleotide sequence disclosure contained in this application does not comply with the requirements for such a disclosure as set forth in 37 C.F.R. 1.821 - 1.825. Applicant's attention is directed to the final rulemaking notice published at 63 FR 29620 (June 1, 1998) and 1211 OG 82 (June 23, 1998). Specifically starting on page 8, paragraph 30, through page 9 polynucleotide sequences are recited, however they are not identified by a sequence identifier. Further, it is noted that neither a sequence listing, a CFR nor supporting declaration has been filed with this application.

Appropriate correction is required.

The absence of proper sequence listing did not preclude the examination on the merits however, **for a complete response to this office action, applicant must submit the required material for sequence compliance.**

Oath/Declaration

The declaration filed October 8, 2002 is in compliance with 37 CFR 1.67(a).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 4 and 5 are rejected under 35 U.S.C. 102(e) as being anticipated by Arap *et al.*

Claim 1 broadly encompasses a method of screening a cDNA library to identify sequences that encode proteins that interact with cell surface protein of a cell. The methodology set forth in the claim as supported by the present specification is methodology commonly referred to as biopanning (paragraph 69). Arap *et al.* teach at the time of filing various methods of biopanning were known. In particular, Arap *et al.* teach a method termed BRASIL (Biopanning and Rapid Analysis of Soluble Interactive Ligands)(paragraph 85). The method of BRASIL can be used to screen for interactions of any variety of cell types for the presence of a encoded protein of interest, and anticipates claim 1 as broadly set forth. Further, Arap *et al.* teach that one can enrich for a given sequence by successive rounds of binding/washing (see for example results in Figure 1 showing three successive biopanning).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Arap *et al.* and Thomson *et al.* (Science, 1998).

As noted above, claim 1 broadly encompasses a method of screening a cDNA library to identify sequences that encode proteins that interact with cell surface protein of a cell and is anticipated by the methods taught by Arap *et al.* Briefly, Arap *et al.* teach at the time of filing various methods of biopanning were known(paragraph 69) and detail a method termed BRASIL (Biopanning and Rapid Analysis of Soluble Interactive Ligands)(paragraph 85). The method of BRASIL can be used to screen for interactions of any cell types for the presence of a encoded protein of interest. While Arap *et al.* provides detailed guidance to practice the methodology in any cell type and provide specific reduction to practice identifying several encoded proteins that interact with cell surface ligands in hematopoietic stem cells of the bone marrow, the reference does not

specifically teach to analyze embryonic stem cells or that the cell expressing the cDNA is a fibroblast (claims 2 and 6), nor that the embryonic stem cell is human (claim 3). At the time of filing putative embryonic stem cells were isolated from several mammalian species including the human (Thomson *et al.*). Thomson *et al.* teach that similarities and differences existed between embryonic stem cells from different species, and may result in observed developmental differences in these species. Thomson *et al.* teaches that human embryonic stem cells can serve as a model for *in vitro* screening and study the differentiation to identify targets for new drugs and genes, or elucidating mechanisms that control differentiation (page 1146). Thomson *et al.* does not teach a specific screening method to identify the agents however highlight several know factors known to be effective in differentiation or the maintenance of stem cells in culture. Therefore, it would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to use rapid and effective methods known in the art to identify proteins important in the maintenance or useful in differentiating ES cells. In addition, it would have been obvious to choose and compare human embryonic stem cells to those of the mouse to define the differences in media component requirements based on their observed culture requirements. One having ordinary skill in the art would have been motivated to screen human embryonic stem cells to identify similarities and differences that exist between themselves and other stem cell known in the art to explain observed characteristics of the ES cells in culture. There would have been a reasonable expectation of success given the results of Arap *et al.* to apply the methodology for the use in the ES cell disclosed in Thomson *et al.* and/or in other species generally known in the art at the time of filing.

Thus, the claimed invention as a whole was clearly *prima facie* obvious.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

US 2003/0049603 A1 Gorochov *et al.* provide evidence that the methodology encompassed by the claimed methods can be effectively used to identify chemokine proteins and variants thereof that interact with a cell of interest.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph Woitach whose telephone number is (571) 272-0739.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Reynolds, can be reached at (571) 272-0734.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group analyst Dianiece Jacobs whose telephone number is (571) 272-0532.

Joseph T. Woitach

Joe Woitach
AU1632